FINDING OF NO SIGNIFICANT IMPACT
FOR

Food Additive Petition 4B4418, submitted by Great Lakes Chemical Corporation, to amend the food additive regulations to provide for the safe use of 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) as a slimicide for use in the manufacture of paper and paperboard intended for food-contact use.

The Environmental Review Team (ERT) has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment prepared using the format described in previous 21 *CFR* 25.31a(a) and on the following:

The additive is expected to degrade upon use to 5,5-dimethylhydantoin (DMH) and hypochlorous and hypobromous acid. The chemicals introduced into the environment through the use of the additive are expected to enter the environment mainly through disposal of the process water from papermaking facilities. We have estimated that a concentration of 1 ppm DMH could enter the environment from the disposal of process water from papermaking plants where the additive is used as proposed. This level is below the toxic concentration criterion, as described in previous 21 *CFR* 25.15(b)(6), based on a reported lowest observed adverse effect level of 29 mg/L for DMH. DMH is also expected to biodegrade in 1-2 days under acclimated conditions. In addition, because the proposed additive is expected to replace other similar halogenated slimicides, the use of the additive is not expected to increase the concentration of halogen ions in paper plant effluent.

The incineration of food-contact materials containing the proposed additive is not expected to have adverse impacts on the environment. Although the proposed additive contains nitrogen and halogens and will produce the acid gases associated with their combustion, the additive is intended to replace other similar additives containing nitrogen and halogens as described under format item 9 of the environmental assessment. Therefore, approval of the proposed additive is not expected to result in a net increase in the levels of acid-gas emissions from the combustion of food-contact paper and paperboard.

Prepared by: Buzz L. Hoffman for Mitchell Cheeseman, Ph.D., Consumer Safety Officer
Division of Petition Control

Date: March 15, 2000

Approved by: Buzz L. Hoffman
Buzz L. Hoffmann, Ph.D., Team Leader
Environmental Review Team
Division of Product Manufacture and Use

Date: March 15, 2000

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date May 16, 2000

From Team Leader, Environmental Review Team (ERT)
Division of Product Manufacture and Use (HFS-246)

Subject FAP 3B4382 - Halogenated hydantoin slimicide
for use in manufacture of paper and paperboard

Lonza, Inc.
c/o Lewis & Harrison
Washington, DC 20001

To Division of Petition Control (HFS-215)
Attention: Vivian Gilliam

On June 14, 1995, FDA published a notice in the *Federal Register* (60 *FR* 31319) announcing that Lonza, Inc. had filed a petition (FAP 3B4382) proposing to amend the food additive regulations in 21 *CFR* 176.300, *Slimicides*, for the safe use of a mixture of 1-bromo-3-chloro-5,5-dimethylhydantoin; 1,3-dichloro-5,5-dimethylhydantoin; and 1,3-dichloro-5-ethyl-5-methylhydantoin as a slimicide in the manufacture of paper and paperboard intended to contact food. The petitioner's environmental assessment (EA) in the original submission was placed on display at the Dockets Management Branch for public review and comment. No comments were received. The environment review of this original EA and subsequent submissions resulted in a finding of no significant impact (FONSI) on August 29, 1997.

Recently, as you have discussed with me, the petitioner requested changes to the nomenclature and in the use level of the subject additive. As a result of these changes, the August 29, 1997, FONSI, and the EA on which the FONSI is based, were no longer appropriate for this action. Because FDA published revised NEPA policies and procedures (62 *FR* 40570, July 29, 1997), including additional categorical exclusions, Dr. Michell Cheeseman (HFS-215) suggested to the petitioner that this action might qualify for one of the new categorical exclusions, *i.e.*, § 25.32(q), and the petitioner submitted a claim for this exclusion in a letter dated December 29, 1999. We concur with the petitioner's claim for this categorical exclusion.

Buzz L. Hoffmann

cc:
HFS-245 Diachenko
HFS-246 RF/Hoffmann
FAP 3B4382

HFS-246:BLHoffmann:eac:3/15/00:p:\eis\blh\3b4382-env.wpd
FT:BLHoffmann:sgm:03/20/00 p:\0pa\dpmu\eis\memos\3b4382.wpd
Refinal: BLHoffmann:sgm:05/17/00